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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA

UNITED STATES OF AMERICA, Plaintiff, v. TOBY CARL MCADAM and GRETA S. ARMSTRONG, individuals d/b/a RISINGSUN HEALTH Defendants.	)	Civil Action No. _____ CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, United States of America, by its undersigned attorneys, having filed its Complaint for Permanent Injunction ("Complaint") against Toby Carl McAdam ("McAdam") and Greta S. Armstrong ("Armstrong"), individuals doing business as Risingsun Health, McAdam Health Enterprises, TCCAH, Inc., and

other business entities owned, operated, maintained, or otherwise by McAdam and/or Armstrong dealing in the same or same type products (hereafter, collectively, "Defendants"), has alleged that:

(a) Defendants violate the Act, 21 U.S.C. § 331(d), by introducing and delivering for introduction, and causing to be introduced and delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved under 21 U.S.C. §§ 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

(b) Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and delivering for introduction, and causing to be introduced and delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded, as defined by 21 U.S.C. §§ 352(f)(1) and 353(b)(1);

(c) Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug to become misbranded, as defined by 21 U.S.C. §§ 352(f)(1) and 353(b)(1), while held for sale after shipment in interstate commerce; and

(d) Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new

animal drugs that are unsafe within the meaning of 21 U.S.C. § 360b(a) and thus adulterated within the meaning of 21 U.S.C. § 351(a)(5);

Defendants, while denying the allegations in the Complaint and disclaiming any liability in connection therewith, having appeared and consented to the entry of this Decree without contest and before any testimony has been taken, solely for the purpose of settling this case, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Complaint states a cause of action against Defendants under the Federal, Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (the "Act").

3. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a), from doing or causing to be done any of the following acts:

A. introducing or delivering for introduction into interstate commerce, holding for sale after shipment in interstate commerce, manufacturing, processing, packaging, labeling, holding, selling, or distributing:

(1) any topically-applied product for human or animal use that contains extracts or components of the Bloodroot plant (*Sanguinaria canadensis*) or the Graviola plant (*Annona muricata*), including, without limitation, any product identified in Schedule A;

(2) any topically-applied product for human or animal use labeled as being similar in its composition or effect to the drugs identified in Schedule A;

(3) any other product that is a new drug, as defined by 21 U.S.C. § 321(p);

(4) any other product that is a new animal drug, as defined by 21 U.S.C. § 321(v)(1); and

(5) any other product that is a dietary supplement as defined under 21 U.S.C. § 321(ff),

unless and until:

(a) an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355 is in effect for such product;

(b) an investigational new drug application ("IND") filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312 is in effect for such product and it is distributed and used solely for the purpose of conducting clinical investigations in strict accordance with the protocol as authorized as part of the IND application;

(c) an approved new animal drug application ("NADA") or abbreviated new animal drug application ("ANADA") filed pursuant to 21 U.S.C. § 360b(b) is effective with respect to such product or such product meets the requirements for the investigational new animal drug exemption pursuant to 21 U.S.C. § 360b(j);

(d) with respect to products identified in subparagraph 3(A)(5) only, any health claims made in the labeling of such product's claims comport with an authorized health claim set forth in 21 C.F.R. §§ 101.72-101.83; and/or

(e) with respect to products identified in subparagraph 3(A)(5) only, any health claims made in the labeling of such product is the subject of a letter of enforcement discretion for a qualified health claim from FDA for such product.

B. Introducing or delivering for introduction into interstate commerce any drug that is misbranded within the meaning of 21 U.S.C. §§ 352(f)(1) or 353(b)(1).

4. Before Defendants may commence distributing any new drug, or continue the distribution of any previously distributed drug that is a new drug, as defined by 21 U.S.C. § 321(p), or a new animal drug, as defined by 21 U.S.C., § 321(v)(1), Defendants shall first notify FDA in writing of their intention to do so, and shall also do the following:

A. For any drug not manufactured and labeled in strict conformance with an FDA over-the-counter ("OTC") monograph under the terms of subparagraph 4(B), Defendants shall demonstrate to FDA that the drug is the subject of: 1) an approved application under 21 U.S.C. §§ 355(a) or (j) by submitting to FDA a copy of FDA's approval letter for such application, 2) an approved application under 21 U.S.C. § 360b(b) by submitting to FDA a copy of FDA's approval letter for such application, or 3) an investigational new drug exemption under 21 U.S.C. § 355(i) or an investigational new animal drug exemption pursuant to 21 U.S.C. § 360b(j) by submitting a copy of the submission(s) made to FDA and an affidavit attesting that a period of 30 days has elapsed since the submission(s) and FDA has not implemented a clinical hold or

otherwise prevented the application from going into effect. In no event may Defendants distribute a drug product that is not the subject of an approved application under 21 U.S.C. §§ 355 or 360(b), or the subject of an investigational new drug exemption under 21 U.S.C. § 355(i) or an investigational new animal drug exemption pursuant to 21 U.S.C. § 360b(j), in either case which application must explicitly authorize manufacture of the drug at Defendant's facility.

B. For any product that purports to be a drug that conforms to the requirements set forth in any of the FDA OTC monographs, 21 C.F.R. Part 330, Defendants may not distribute such drug products unless and until:

(1) Defendants retain, at Defendants' expense, an independent person or persons (the "drug monograph expert"), who is without any personal or financial ties to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to review the labeling of Defendants' OTC drug(s) to determine whether such product(s) comply with the applicable OTC drug monograph and other labeling requirements of the Act and FDA regulations. Defendants shall notify FDA in writing of the identity and qualifications of the drug monograph expert as soon as they retain such expert;

(2) The drug monograph expert performs a comprehensive review of the OTC drug's proposed labeling to determine whether the product strictly

conforms to an applicable FDA OTC monograph and all labeling requirements, including 21 C.F.R. Part 201, and that the OTC drug is not otherwise misbranded;

(3) The drug monograph expert certifies in writing to FDA that: (a) he or she has reviewed the OTC drug and its labeling; (b) the OTC drug labeling conforms to the requirements of an OTC drug monograph and all applicable labeling requirements, including 21 C.F.R. Part 201; and (c) the OTC drug is not otherwise misbranded. As part of this certification, the drug monograph expert shall include a full and complete detailed report of the results of his or her labeling review, including references to the OTC monograph and labeling regulations addressed in the process of conducting the labeling review;

(4) Defendants have provided to FDA any additional information requested by FDA after FDA's review of the drug monograph expert's certification pursuant to subparagraph 4(B)(3); and

(5) FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in subparagraphs 4(B)(1)-(4). In no circumstance may FDA's silence be construed as a substitute for written notification.

5. Before Defendants may commence manufacturing or distributing, or continue the manufacture or distribution of, any product that is not a new drug or

an OTC drug, but which product is either intended to be ingested by humans or animals, or intended to be topically applied to humans or animals (each such product an "Other Product"), Defendants shall first notify FDA in writing of their intention to manufacture or distribute such Other Product, and shall retain at their own expense an independent person or persons (the "labeling expert") who is without any personal or financial ties to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to review Defendants' product labeling and determine whether such Other Product(s) comply with the applicable requirements of the Act. The labeling expert may be the same person(s) as the drug monograph expert. Defendants shall notify FDA in writing of the identity and qualifications of the labeling expert as soon as they retain such expert. With respect to any Other Product that Defendants intend to manufacture and/or distribute, the labeling expert shall perform a comprehensive review to determine whether Defendants have omitted all claims from their labeling that would cause such Other Product to be a drug and/or that constitute unapproved or unauthorized health claims within the meaning of the Act. Before Defendants may manufacture and/or distribute any Other Product, the labeling expert shall submit a written report to FDA analyzing whether Defendants are

operating in compliance with the Act and whether each such Other Product may be manufactured and/or distributed in compliance with the Act.

6. Within thirty (30) calendar days of entry of this Decree, Defendants shall, under FDA supervision, destroy all of the following items that are in Defendants' possession, custody and/or control: (a) all of the drug products identified in Schedule A; (b) any product labeled as being similar in composition or intended use to the drugs identified in Schedule A; and (c) any other new drug, as defined by 21 U.S.C. § 321(p). Defendants shall reimburse FDA for the supervision of the destruction at the rates set forth in paragraph 12 of this Decree. Defendants shall not dispose of any drug products in a manner contrary to any federal, state, or local laws, including but not limited to, the National Environmental Policy Act of 1969.

7. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. Violates 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new animal drugs that are not the subject of an approved NADA, an approved ANADA, a conditional approval, or a relevant index listing for minor species, and which do not meet the requirements for the investigational new animal drug exemption. See 21 U.S.C. §§ 360b(a)(1), 360b(j);

C. Violates 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded; or

D. Violates 21 U.S.C. § 331(k), by causing an article of drug to become misbranded while held for sale after its shipment in interstate commerce.

E. Violates 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce any article of drug that is adulterated within

the meaning of 21 U.S.C. § 351 or any dietary supplement that is adulterated within the meaning of 21 U.S.C. § 342(g)(1);

F. Violates 21 U.S.C. § 331(k) by causing the adulteration of any article of drug within the meaning of 21 U.S.C. § 351 or any dietary supplement within the meaning of 21 U.S.C. § 342(g)(1), while such article of drug or dietary supplement is held for sale after shipment of one or more components in interstate commerce.

8. Nothing in this Decree shall prohibit Defendants from manufacturing and distributing dietary supplements as defined under 21 U.S.C. § 321(ff) provided that the Defendants fully comply with the provisions of this Decree.

9. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' places of business and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted prompt access to Defendants' place(s) of business, including all buildings, equipment, in-process and finished materials and products, containers, labeling and other materials therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, labels, labeling, and other

promotional materials; and to examine and copy all records relating to the receipt, manufacture, processing, packaging, labeling, holding, sale, and distribution of any and all of Defendants' products, including components, in order to ensure continuing compliance with the terms of this Decree. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

10. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, analyses of samples, labeling, promotional materials, or any other information, that Defendants have violated the Act, applicable regulations, or this Decree, or that additional corrective actions are necessary to achieve compliance with the Act, applicable regulations, or this Decree, FDA may, as and when it deems necessary in its sole discretion, direct Defendants, in writing, and order Defendants to take appropriate corrective action, including, without limitation and immediately, one or more of the following actions:

A. Cease manufacturing, processing, packaging, labeling, holding, selling, and/or distributing any or all drugs and/or dietary supplements;

B. Recall, at Defendants' expense, any drug or dietary supplement that is adulterated, misbranded, unapproved, or otherwise in violation of this Decree, the Act, or its implementing regulations; or

C. Take any other corrective action(s) as FDA deems necessary to protect the public health or to bring Defendants and their products into compliance with the Act, applicable regulations, and this Decree.

11. Any cessation of operations as described in paragraph 10 shall continue until FDA notifies Defendants in writing that Defendants appear to be in compliance with the Act, applicable regulations, and this Decree, and that Defendants may resume operations.

12. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in this Decree or that FDA deems necessary to evaluate Defendants' compliance with this Decree at the standard rates prevailing at the time the activities are accomplished. As of the date that this Decree is signed by the parties, these rates are: $87.57 per hour and fraction thereof per representative for inspection work; $104.96 per hour or fraction thereof per representative for laboratory analytical or review work; $0.50 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem

rate for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

13. Within fifteen (15) calendar days of entry of this Decree, Defendants shall provide a copy of this Decree, personal delivery with acknowledgement of receipt or certified mail (restricted delivery, return receipt requested), to each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including "doing business as" entities)(hereafter collectively referred to as "associated persons"). Within thirty (30) calendar days of entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all associated persons who have received a copy of this Decree and the manner of notification. In the event that Defendants become associated, at any time after the entry of this Decree, with new associated persons, Defendants shall: (a) within fifteen (15) calendar days of such association, provide a copy of this Decree to each such associated person by personal service or certified mail (restricted delivery, return receipt requested), and

(b) on a quarterly basis, notify FDA in writing when, how, and to whom the Decree was provided.

14. Defendants shall notify FDA, in writing at least fifteen (15) calendar days before any change in ownership, character, or name of any of their businesses, including incorporation, reorganization, bankruptcy, assignment, sale resulting in the emergence of a successor business or corporation, or any other change in the structure or identity of the Defendants' business, or the assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Any Defendant who provides notification to FDA under this paragraph shall provide a copy of this Decree to any prospective successor or assign at least ten (10) calendar days prior to any sale or assignment. Such Defendant(s) shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

15. A party may at any time petition the other party in writing to extend any deadline provided for herein, and such extension may be granted by the other party in its sole discretion without seeking leave of Court.

16. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Decree shall be addressed to the

Director, FDA Seattle District Office, 22201 23rd Drive SE, Bothell, WA 98021-4421.

17. If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on motion of the Plaintiff, Defendants shall pay to the United States of America: one thousand dollars ($1,000.00) in liquidated damages, and an additional sum of one thousand dollars ($1,000.00) in liquidated damages for each day the violation of the Act, its implementing regulations, and/or this Decree continues. The amount of liquidated damages imposed under this paragraph shall not exceed eighty thousand dollars ($80,000) per defendant in any calendar year. Any motion filed by the Plaintiff pursuant to this paragraph shall specify the noncompliance giving rise to the motion. In addition, should Defendants distribute any unapproved new drug(s), they shall, in addition to the foregoing, also pay to the United States as liquidated damages a sum equal to three times the retail value of such drug(s). Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the power of the Court to impose, additional criminal or civil penalties or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

18. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, administrative and court costs, and any other costs or fees, including overhead, related to such contempt proceedings.

19. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final and Defendants shall abide by the decisions of FDA. If contested, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

20. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED:

Dated this ____ day of _____, 2010.

_____
UNITED STATES DISTRICT JUDGE

Entry consented to:

FOR DEFENDANTS

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Counsel for Toby Carl McAdam

GRETA S. ARMSTRONG, individually

DAVID L. ROSEN,
Counsel for Greta S. Armstrong

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